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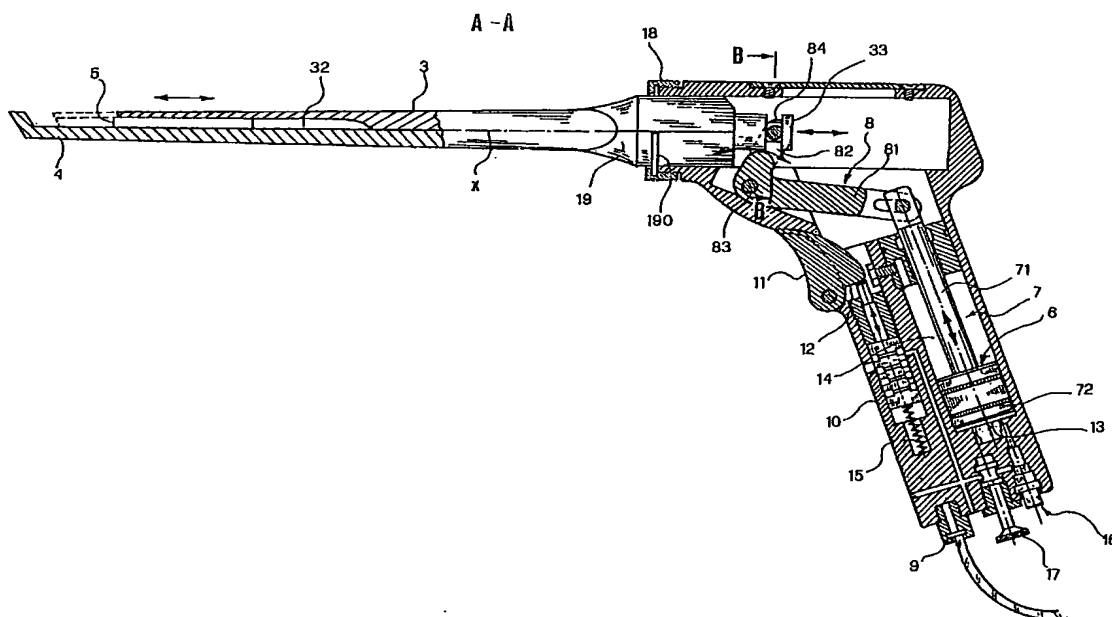
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(54) Title: **OSTEOTOM**



(57) Abstract: Osteotom (1) for the removal of bone and of bone tumors, as well as of ligaments and fibrocartilaginous tissue, during surgery, comprising a pair of blades (3, 4) slidably coupled so that respective distal ends (31, 41) thereof be closable the one against the other for the removal of a bone fragment (O), pneumatic propelling means (6) for the blades (3, 4), and a trigger (11) for the operation of the propelling means (6) by a user (Fig. 5B).

OSTEOTOM**Description**

5 The present invention relates to a surgical device, and in particular to an osteotom for the removal of bone and of bone tumors, as well as of ligaments and fibrocartilaginous tissue, during surgery, and in particular to an osteotom of the type comprising a pair of blades slidably coupled so as to be closable the one against the other at respective distal ends.

10 Osteotoms for the removal of bone tissue are known, which comprise a pair of parallel blades, the one slidable onto the other so that a bone fragment may be clamped between respective distal ends of the blades themselves and then removed. The sliding of one blade onto the other is generated directly by a surgeon via a handle formed by two rotatably connected levers, each one integral to a respective blade. By forcing said levers the one
15 against the other, the surgeon actually closes the blades.

Such known-art osteotoms also envisage the interposition of an elastic resisting element between said levers, said element being apt to return the latter – and therefore the blades integral thereto – to the initial resting position when the surgeon releases the levers themselves.

20 Over the last five decades, the above described known-art osteotoms have been widely used for surgery requiring the removal of bone tissues, like, e.g. spinal, neurological and orthopedic surgery, ear, nose and throat surgery, maxillo-facial and thoracic surgery, and so on.

However, such known-art osteotoms suffer from some relevant drawbacks.
25 In particular, the present invention is based on the observation that such osteotoms, in order to be operated and to produce the removal of a bone fragment, require the exertion of a remarkable force by the surgeon, also due to the fact that the latter should overcome the resistive force of said resisting element. As surgery generally requires a continuous and repeated use of the
30 osteotom, the operation modes of the known-art osteotoms tire the surgeon, and in particular the osteotom-operating limb. Moreover, in the effort of operating the osteotom, the surgeon could impart undesired swinging motions thereto. All of this affects surgery accuracy and safety, and prolongs the related times.

35 Hence, the technical problem underlying the present invention is that of providing a surgical device, and in particular an osteotom, allowing to

overcome the drawbacks mentioned hereto with reference to the known art. Such a problem is solved by a surgical device according to claim 1.

According to the same inventive concept, the present invention further relates to a surgery kit according to claim 24.

5 The invention further provides a surgery apparatus according to claim 26.

Preferred features of the present invention are provided in the dependent claims thereof.

The present invention provides some relevant advantages. The main advantage lies in the fact that the surgical procedure is optimized in terms of
10 accuracy, safety and times. In fact, the presence of propelling means for the slidable blade interposed between the latter and suitable operation means apt to be handled by the user dispenses the surgeon from directly providing the operating force of the osteotom blades. Hence, during surgery the operator's attention may entirely focus on the structures to be removed.

15 Other advantages, features and the modes of employ of the present invention will be made apparent in the detailed description of some embodiments thereof, given by way of example and not for limitative purposes. It will be made reference to the figures of the annexed drawings, wherein:

20 Figure 1 shows a top perspective view of an embodiment of the osteotom according to the present invention;

Figure 2 shows a bottom perspective view of the osteotom of Figure 1,

Figure 3 shows a longitudinal sectional view of the osteotom of Figure 1;

25 Figure 3A shows a cross sectional view of the osteotom of Figure 1, taken along line B-B of Figure 3;

Figure 3B shows a schematic representation of a portion of a pneumatic circuit of the osteotom of Figure 1;

Figures 4A and 4B each show a side view of a detail of the blades of the osteotom of Figure 1 and of a variant of such detail, respectively; and

30 Figures 5A to 5C illustrate the modes of employ of the osteotom of Figure 1, each showing a perspective view thereof during use in surgery.

Referring initially to Figure 1, an osteotom according to an embodiment of the invention is generally indicated by 1.

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The osteotom 1 comprises a main body 2 - or handpiece - apt to be handled by a user, and a pair of blades, and specifically a first blade 3 and a second blade 4, which in the present embodiment are removably connected to the main body 2 according to modes that will be illustrated later on.

5 The main body 2, serving as chassis of the osteotom 1, comprises a portion 20 apt to be handled by the surgeon by a single hand; the other hand may be used to hold the blades during surgery.

The main body 2 further provides a top closure panel 21 to allow access to components internal thereto.

10 The blades 3 and 4 are located parallel and side-by-side and are slidably coupled the one to the other, as in known-art osteotoms.

As it is shown in greater detail in Figure 4, and always as in known-art osteotoms, such blades 3 and 4 have respective cutting distal ends, indicated by 31 and 41, respectively, mutually closable the one against the other for the removal of a bone fragment or other biological material during surgery. For this purpose, the second blade 4 has, at the end 41, a slant with respect to the predominant direction of development of the blades themselves. In particular, in Figure 4A there has been depicted a blade 4 having, at the distal end 41, a slant of about 30 degrees with respect to the vertical.

20 However, a person skilled in the art will understand that the invention is fit to be used in association with blades having any tilt whatsoever. For example, as it is shown in Figure 4B, the invention may be associated with a second blade 40 the distal end 410 of which has a tilt of about 90° with respect to the horizontal.

Referring now to Figure 3, in order to produce said closing of the blades 3 and 4, as already mentioned above the first blade 3 is slidable onto the second blade 4. The first blade 3 has a longitudinal groove 32 faced onto the second blade 4 for allowing the parallel sliding between the two blades. In order to prevent bone fragment entrapment within such groove 32, i.e. between the blades 3 and 4, an elongate element 5 is longitudinally secured onto the second blade 4. When the first blade 3 is moved backward with respect to the second blade 4, this element 5 prevents dragging of the bone fragment by the first blade itself.

35 The main body 2 internally houses propelling means for the first blade 3,

globally indicated by 6 and apt to determine the sliding of the latter with respect to the second blade 4.

In the present embodiment, the propelling means 6 is of pneumatic type. In particular, it comprises a cylinder-piston system 7 and a motion transmission member 8 rotatably coupled to the stem 71 of said piston at respective ends.

In the present embodiment, the transmission member 8 is substantially L-shaped, comprising in particular a first arm 81, which is rotatably connected to the stem 71 at a free end thereof, and a second arm 82 integral to the first arm 81 and rotatably connected, at the end of the member 8 opposed to that connected to the stem 71, to the first blade 3. The specific connection modes between the member 8 and the first blade 3 provided in the present embodiment will be detailed hereinafter.

Moreover, the transmission member 8 is hinged to the main body 2 at a central region thereof of intersection of said arms 81 and 82 by a fulcrum element 83. Therefore, the transmission member 8 forms a sort of first class lever whose motive force is that exerted by the piston and whose resistive force is that associated with the first blade 3 and the bone fragment entrapped between the blades 3 and 4. In order to attain an advantageous motive force/resistive force ratio, the first arm 81 is longer than the second arm 82 and preferably in a 3:1 ratio therewith.

The pneumatic propelling means 6 further comprises an intake 9, in form of pipe holder, for supplying compressed air from the outside, and in particular for connecting the osteotom 1 to the pneumatic system of the operating theatre.

Therefore, the propelling means 6 comprises a pneumatic circuit interposed between said intake 9 and said cylinder-piston system 7 for the controlled supplying of compressed air at both sides of the piston body 72.

Said pneumatic circuit is implementable with known components and modes, and in particular it comprises a compressed air supply channel network and an associated one- or plural-way valve system. In the section of Figure 3, only a few of the channels and of the other components of such circuit are visible. Instead, a schematic global depiction of the circuit itself is shown in Figure 3B.

Hence, with reference to Figures 3 and 3B, said pneumatic circuit comprises a plural-way valve 10. The latter directly cooperates with an operation trigger or push button 11, located at the portion 20 of the main body 2 and apt to be

handled by the surgeon for determining the operation of the propelling means 6 and therefore the closing of the first blade 3 onto the second blade 4.

5 The overall arrangement is such that, when the user presses the trigger 11, the latter, insisting with one surface 12 thereof onto the body of the valve 10, determines the lowering of said valve body and the entailed compressed air supplying to a cylinder region 13 located below the piston body 72. Concomitantly, there is allowed the outlet of air from the cylinder region 14 located above the piston body 72. Then, the air inflow in the bottom region 10 13 determines the upward motion of the piston, i.e. its motion towards the transmission member 8. The latter, by effect of said piston motion, is induced in rotary motion, as it is indicated by the arrow of Figure 3, thereby determining the advance of the first blade 3 with respect to the second blade 4.

15 When the surgeon releases the trigger 11, a mechanism specular to the above-described one is determined. In particular, an elastic resisting member 15 automatically returns the body of the valve 10 to the initial position, determining an inflow of air to the cylinder top region 14 and an outflow of the air contained in the bottom region 13.

20 Hence, it will presently be appreciated that in order to produce the motion of the top blade 3 the surgeon should merely apply a light force onto the trigger or push button 11 in order to overcome the resistive force of the elastic element 15. The operation via a trigger or equivalent system, requiring a minimal force, causes no undesired motions or swinging of the entire osteotom, as instead occurring in known-art systems. Moreover, there are no 25 problems of the osteotom interfering with other instruments or elements in the surgical field, like e.g. self-retaining retractors.

As illustrated hereto, the propelling means 6 is operable by a user via said trigger 11. The overall configuration of the described pneumatic system is 30 such that, according to the speed at which the surgeon presses onto the trigger 11, there is attained an adjustment of the advance speed of the first blade 3 with respect to the second blade 4, osteotomic force exerted onto the material to be removed being equal. Therefore, the system of the invention enables to adjust the blade-sliding speed with no concomitant 35 osteotomic power loss.

Of course, variant embodiments can provide operation means differing from

said trigger 11.

Always with reference to Figures 3 and 3B, the osteotom 6 further comprises means 16 for adjusting the closing speed of the blades 3 and 4, which in the present embodiment is implemented by a flow regulator operable at the base of the main body 2 and partially visible also in Figure 2. This flow regulator 16 is apt to control the flow resistance at the pneumatic circuit portion associated with the cylinder bottom region 13.

It will be appreciated that the hereto-introduced adjusting means is particularly useful for the adaptability of the instrument to osteotomic blades of different size. Moreover, also this means allows an adjusting of the advance rate of the first blade 3 with respect to the second blade 4, osteotomic force being equal.

Moreover, as it is schematically shown in Figure 3B, the osteotom 1 may further allow an adjustment of the closing force of the blades 3 and 4 by a pressure regulator R located externally thereto and incorporated in the pneumatic system of the operating theatre.

Of course, variant embodiments may envisage implementation modes of the rate and/or of the closing force of the osteotom blades alternative to the abovedescribed ones.

In the present embodiment, the osteotom 1 also comprises means 17 for inhibiting operation of the propelling means 6. In the present example, such means 17 comprises a block valve, it also indicated by 17, apt to deny the pneumatic circuit portion associated with the cylinder bottom region 13. The means 17 are operable by the surgeon, e.g. via a simple push button mechanism located at the base of the main body 2, in order to allow a safe pass of the osteotom to other operators, e.g. to a medical assistant. In fact, when such means 17 is inserted there is no risk that the assistant, accidentally pressing the trigger 11 while cleaning the blades 3 and 4, be wounded due to the abrupt closing thereof.

Hereinafter, with reference to Figures 3 and 3A, there will be detailed the modes of connecting the first blade 3 to the second arm 82 of the element 8.

In the present embodiment, the arm 82 ends in a substantially U-shaped end 84, which is apt to removably and rotatably receive a knob-shaped proximal end 33 of the first blade 3. In particular, with reference to the configuration of Figure 3, the first blade 3 can rotate within the U-shaped portion 84, and therefore with respect to the transmission member 8, about an axis of

rotation X parallel to the blade itself. Moreover, always with reference to the configuration of Figure 3, the first blade 3 may be disconnected from the element 8 by a mere downward extracting motion apt to disengage the portion 84 from the portion 33.

5 As it is shown always in Figure 3, and also with reference to Figures 5A and 5B, the removable connection of the blades 3 and 4 to the main body 2 – and then, in short, to the propelling means 6 – is further entrusted to a ring nut 18 apt to be screwed at a threaded end face of the main body 2 itself. This ring nut 18 cooperates with a sleeve 19 for retaining the blades 3 and 4
10 so as to block the latter with the main body 2. In particular, the first blade 3 is slidable within the sleeve 19 so as to be connectible to the transmission member 8 in the abovedescribed manner. The second blade 4 is instead integral to the sleeve 19 and it is apt to be blocked with the ring nut 18 by a tooth 190.

15 According to the hereto-described arrangement, when the ring nut 18 is firmly tightened onto the main body 2, the sole relative degree of freedom between the latter and the blades 3 and 4 is that associated with the sliding of the first blade 3 onto the second blade 4. However, as it is shown in Figure 5B, it suffices to slightly loosen the ring nut 18 with respect to the
20 main body 2 in order to allow the blades 3 and 4 to rotate integrally the one to the other with respect to the main body 2 about said axis of rotation X substantially parallel to the blades themselves. Thus, the osteotomic blades may be rotated on a continuous 360 degrees field.

This aspect of the invention, i.e. the fact that the blades 3 and 4 are rotatable
25 with respect to the main body 2, allows the operator to keep the latter – and therefore the hand holding and operating the instrument – always in the most suitable and comfortable position, and to position the osteotomic blades 3 and 4 with any working angle in the 360 degrees with respect to the body 2. This constitutes a relevant advantage with respect to the known-art systems,
30 in which the operator is instead forced to rotate the entire instrument to arrange the blades in a desired angle, or even to change several instruments during the same surgery, each instrument being preset with blades having a fixed angle with respect to the operation levers.

It will further be appreciated that the removable connection between blades 3
35 and 4 and main body 2 and the hereto-described modes of such connection allow the operator to easily interchange the pair of blades connected to the

main body, so as to always use the blades most suitable for the specific surgery to be carried out. In particular, the change of the pair of blades can take place with a few simple motions, i.e.: rotating the ring nut 18; pressing the trigger 11 to produce an advance of the member 8 and therefore of the blade 3 connected thereto; and disengaging the connection between the knob portion 33 of the blade 3 and the U-shaped end 84 of the second arm 82. Then, with reversed motions, the connection of the new pair of blades is attained.

Hence, the osteotom of the invention may also be provided in form of surgery kit, such a kit comprising said main body 2 apt to be handled by a surgeon and a plurality of pairs of osteotomic blades removably connectible thereto, i.e. to the propelling means for the slidable blade.

Such a provision in form of kit also entails the advantage of smaller dimensions of the entire assembly on operating tables as well as in sterilization baskets with respect to the traditional osteotoms, in which to each blade type there correspond an entire different instrument.

Moreover, the removable connection between the main body – and therefore the propelling means – and the blades also entails the advantage of requiring no disassembly or replacement of the entire instrument when the blades deform or wear out.

By now, the modes of employ of the osteotom 1 will have been made apparent, and will only briefly be recalled herein.

The surgeon can select and rapidly mount the osteotomic blades 3 and 4 that are most suitable for the surgery or surgery step to be carried out onto the main body 2 according to the modes described above.

Then, previously to the blade mounting, the osteotom 1 is connected to the pneumatic system of the operating theatre via the intake 9.

At this point, as it is shown in Figures 5A to 5C, the surgeon may operate – easily and with a negligible force – the propelling means 6 via the trigger 11 and remove the desired tissue portions O.

During surgery, it is also possible to rotate the blades 3 and 4 with respect to the handle 20, to adjust the blade operating rate by the trigger 11 itself or by the means 16, or even to adjust the closing force by the regulator R, according to the modes already illustrated hereto.

Moreover, when the osteotom 1 is passed to an assistant, or anyhow when it is not to be used, there may be inserted the inhibiting means 17 for ensuring operator's safety.

5 By now, it will be better appreciated that the device of the invention allows to improve the accuracy of surgery.

In fact, first of all, as already hinted above, the surgeon may concentrate onto the action of the blades instead of being diverted by the need to directly operate them through levers. The involvement of the surgeon's cerebral
10 cortex, and in particular of the premotor gyrus, is near-negligible, consisting of the repeated pressure of the sole trigger 11, whereas the visual cortex is involved in an exclusive and prominent manner to the end of recognizing the structures involved in the osteotomic act (e.g.: radicular cysts, dural casing, peridural venous sinuses, cranial base vascular and nervous structures,
15 etc.).

It will also be appreciated that the device of the invention, by providing propelling means for the blades and operation means for the latter, rather than a direct operation of the blades by a user, increases and steadies the closing force of the osteotomic blades, regardless from the extent of the
20 force applied onto the trigger by the operator carrying out the surgery.

Moreover, the provision of suitable operation means 11 for the propelling means 6 allows to slow down or instantaneously stop the operation of the blades – by a lower pressure or the release of the trigger - when an interposition of structures not destined to be removed is suspected. In these
25 cases, the reaction times of the surgeon and of the instrument are markedly reduced with respect to the conventional systems requiring a manual operation of the blades.

Furthermore, the osteotom is less bulky than the known art systems, which are bound to the bulkiness associated with the opening of the operation
30 levers. This prevents the occurrence of the abovementioned problems of interference of the osteotom with other instruments or elements in the surgical field.

Moreover, in known-art systems the need to grasp in one hand the blades wide apart is another relevant drawback, since such a holding is
35 cumbersome for a small-handed surgeon. Evidently, this drawback as well is

overcome by the osteotom of the invention, in which the main body may have a reduced-size holding portion.

Moreover, it will be appreciated that the pneumatic implementation of the propelling means as above is easy, cost-effective and perfectly compatible
5 with the structures already present in the operating theatre. Furthermore, such implementation requires no lubrication systems possibly incompatible with operating room sterility requirements. Additionally, pneumatic propelling is perfectly and immediately compatible with the required blade closing forces and speeds.

10

It will be understood that the present invention is susceptible of several embodiments and variant embodiments alternative to those described hereto.

15

For example, the osteotom of the invention may provide means for coupling to or for cooperating with a neuronavigation system, e.g. one or more position sensors, and hence be employed in the context of a surgery apparatus comprising said neuronavigation system. This allows a mapping of the bone to be removed, and therefore the real-time assessment of the work already carried out and to be carried out, optionally with a three-dimensional
20 virtual representation of the anatomic structures to be preserved, studied with MR, TC, and scopy. Embodiment variants could also provide an integration with robotized systems apt to automatically carry out some repetitive and pre-codified surgical procedures.

25

The present invention has been hereto described with reference to preferred embodiments thereof. It is understood that other embodiments may exist, all falling within the concept of the same invention, and all comprised within the protective scope of the claims hereinafter.

Claims

1. A surgical device (1) apt to the removal of bone, cartilaginous and the like tissues during surgery, comprising:
 - 5 – a pair of side-by-side blades (3, 4), slidably coupled so that respective distal ends (31, 41) thereof be closable the one against the other for the removal of a tissue fragment (O);
 - propelling means (6), connected or connectible to a blade (3) of said pair (3, 4) and apt to determine the sliding thereof with respect to the other (4)
10 of said blades; and
 - operation means (11) for the operation of said propelling means (6) by a user.
2. The device (1) according to claim 1, wherein said slidable blade (3) of said pair (3, 4) is removably connected or connectible to said propelling means
15 (6).
3. The device (1) according to claim 1 or 2, wherein the arrangement is such that said slidable blade (3) of said pair (3, 4) automatically returns to a resting position when the user releases said operation means (11).
4. The device (1) according to any one of the preceding claims, wherein the
20 arrangement is such that the blades (3, 4) of said pair can rotate with respect to said operation means (11), during surgery, about an axis of rotation (X) substantially parallel to the blades themselves.
5. The device (1) according to any one of the preceding claims, wherein said operation means comprises a trigger device (11).
- 25 6. The device (1) according to any one of the preceding claims, comprising a main body (2) apt to be handled by a user and connected or connectible to said pair of blades (3, 4).
7. The device (1) according to the preceding claim, wherein said operation means (11) are located at said main body (2).
- 30 8. The device (1) according to the preceding claim, wherein said main body (2) comprises a portion (20) apt to be handled by a user by a single hand, and wherein said operation means (11) are located at said portion (20).
9. The device (1) according to any one of the claims 6 to 8, wherein said propelling means (6) is received within said main body (2).

10. The device (1) according to any one of the claims 6 to 9, wherein the blades (3, 4) of said pair are removably connected or connectible to said main body (2).

5 11. The device (1) according to any one of the preceding claims, wherein said propelling means (6) are of a pneumatic type.

12. The device (1) according to the preceding claim, wherein said propelling means (6) comprises a piston (7) apt to produce the sliding of said slidable blade (3) of said pair of blades (3, 4).

10 13. The device (1) according to the preceding claim, wherein said piston (7) is coupled to said slidable blade (3) of said pair of blades (3, 4) by interposition of a motion transmission member (8).

14. The device (1) according to the preceding claim, wherein said motion transmission member (8) is a lever rotatably connected at opposed ends thereof to said slidable blade (3) of said pair of blades (3, 4) and to the stem (71) of said piston (7), respectively, and moreover rotatably connected to a chassis (2) of the device (1) at a central portion thereof.

15 15. The device (1) according to any one of the claims 11 a 14, wherein said propelling means (6) comprises a supply valve (10) of a or of said pneumatic piston (7) and said operation means (11) cooperates with said supply valve (10).

16. The device (1) according to any one of the claims 11 a 15, wherein said propelling means (6) comprises an intake (9) for supplying compressed air from the outside.

17. The device (1) according to any one of the preceding claims, comprising means (R) for adjusting the closing force of the blades (3, 4).

18. The device (1) according to any one of the preceding claims, comprising means (11, 16) for adjusting the relative sliding speed of the blades (3, 4) of said pair.

19. The device (1) according to the preceding claim when dependent from any one of the claims 11 to 16, wherein said means for adjusting the sliding speed comprises flow adjusting means (16).

20. The device (1) according to claim 18 o 19, wherein said operation means (11) are such that the relative sliding speed of the blades (3, 4) of said pair depends on the user's speed of handling the operation means themselves.

35 21. The device (1) according to any one of the preceding claims, comprising

means (17) for inhibiting operation of said propelling means (6).

22. The device (1) according to any one of the preceding claims, comprising means (5) for preventing bone fragment entrapment between the blades (3, 4) of said pair.

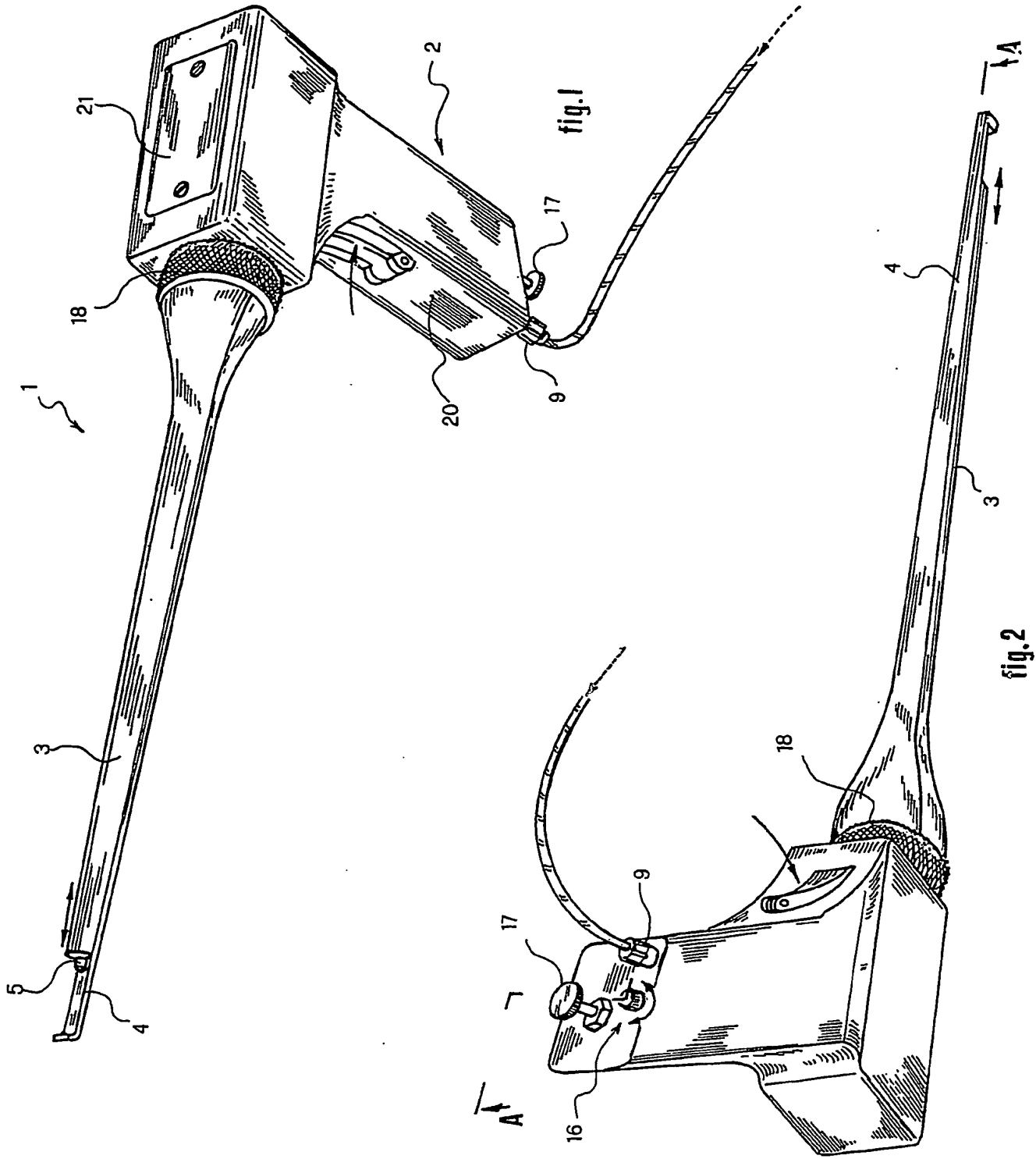
5 **23.** The device (1) according to any one of the preceding claims, comprising means for cooperating with a neuro-navigation system.

24. A surgery kit, comprising a surgical device (1) according to any one of the preceding claims and a plurality of osteotomy blades (3, 4) removably connectible to said propelling means (6).

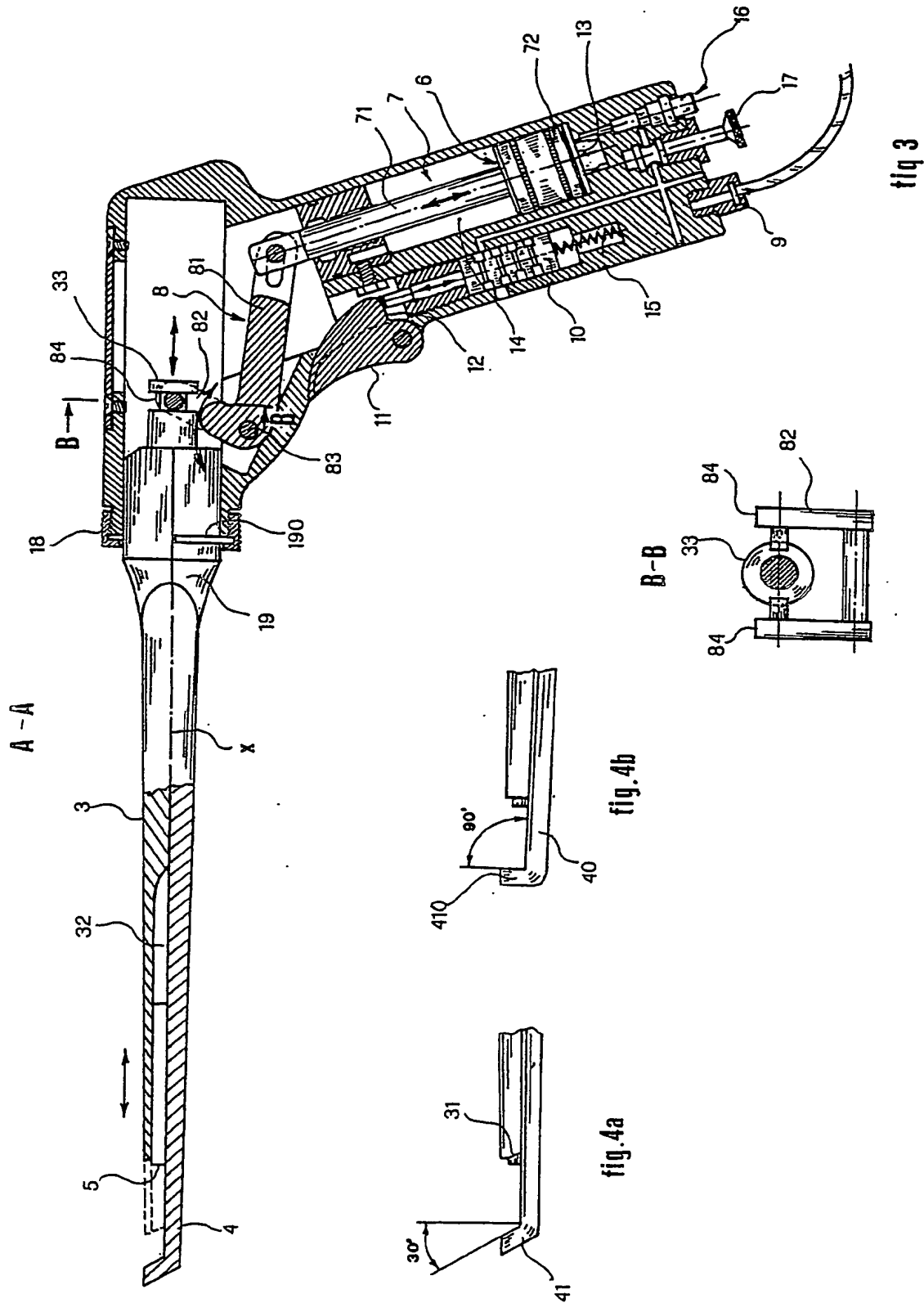
10 **25.** The kit according to the preceding claim, comprising means (9) for connection with pneumatic supply means.

26. A surgery apparatus, comprising a surgical device (1) according to any one of the claims 1 to 23 and a neuro-navigation system associated thereto.

- 1/4 -



- 2/4 -



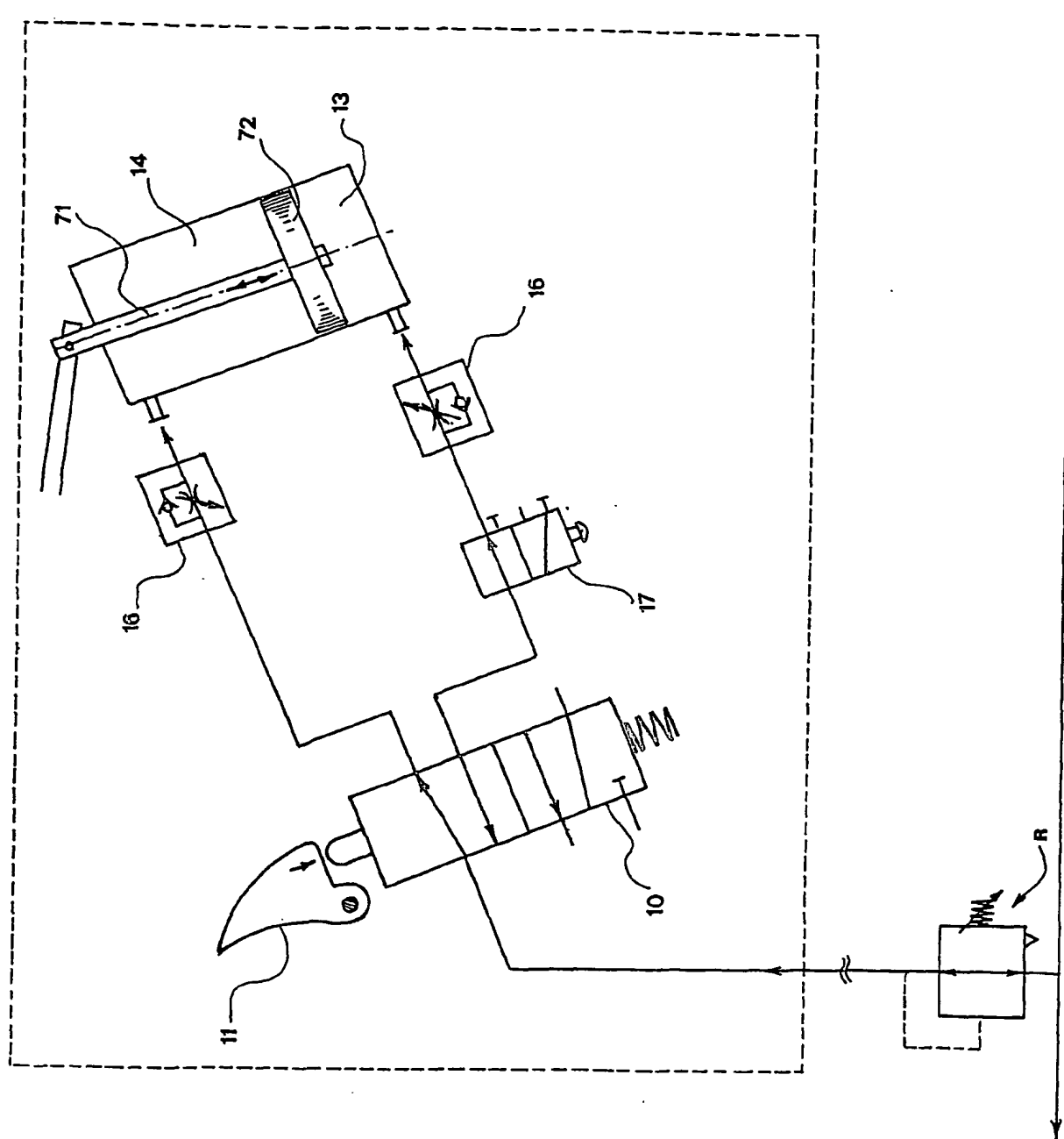
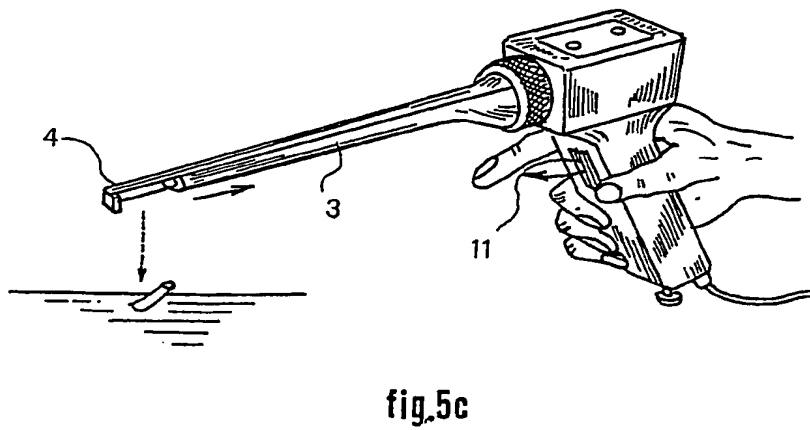
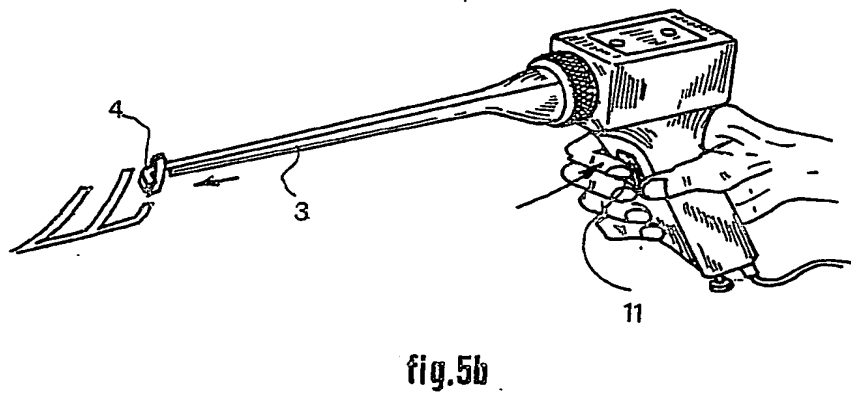
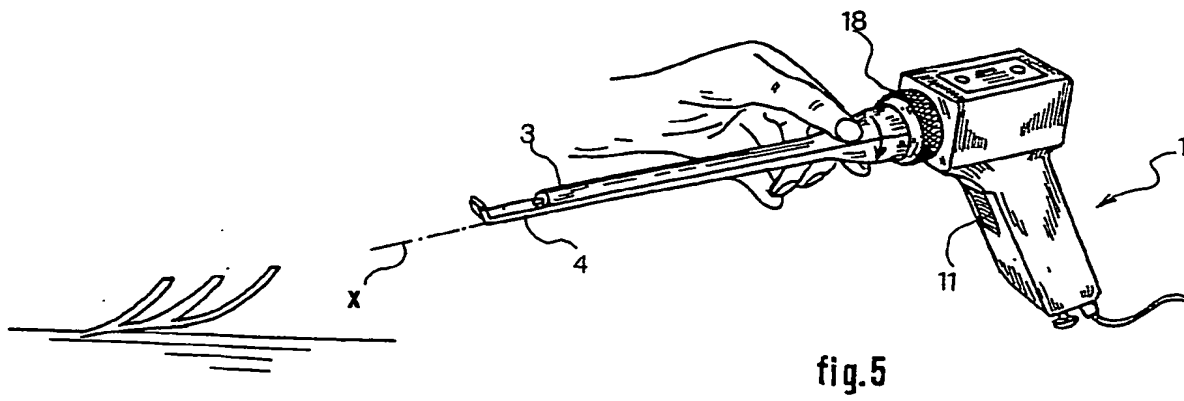


fig. 3b

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B B25C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 752 161 A (BENT J) 14 August 1973 (1973-08-14)	1-13, 15, 16, 18, 19
Y	column 3, line 58 - column 8, line 34	14, 17, 21-23
Y	US 2 625 682 A (JOSEPH CRISTIANO) 20 January 1953 (1953-01-20)	14
Y	US 4 848 338 A (DE SATNICK ALLEN H ET AL) 18 July 1989 (1989-07-18)	17, 21
Y	WO 02 34144 A (LIU MINGYAN ; JOSSE LOIC (FR); SDGI HOLDINGS INC (US); FOLEY KEVIN) 2 May 2002 (2002-05-02) claim 23	23
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International Application No.

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